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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Keil & Weinkauf
1350 CONNECTICUT AVENUE N.W
Washington, DC 20036

EXAMINER	
LOCKARD, JON MCCLELLAND	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,094	GARCIA-LADONA ET AL.	
	Examiner	Art Unit	
	Jon M Lockard	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *3,8-10 and 13-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-7,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 February 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/29/2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (claims 1-2, 11, and 12 (in part) in so far as they are drawn to methods of treatment in a human by administering a compound that modifies or induces homer expression) in the Response and Amendment filed on 28 October 2004 is acknowledged. Applicant did not traverse the restriction requirement but amended claims 4 and 7 so that claims 4-7 fit under the rubric of the method detailed in Group I of the previous Office Action (24 September 2004). Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP §818.03(a)).

2. In the interest of expedited prosecution pursuant to MPEP §707, the Examiner will examine claims 1-2, 4-7, and 11-12, and recognizes Applicant's right to pursue additional subject matter in other applications.

3. Claims 3, 8-10, and 13-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

4. The restriction requirement is still deemed proper and is therefore made FINAL.

Status of Application, Amendments, and/or Claims

5. The response filed 28 October 2004 has been entered in full. Claims 3, 8-10, and 13-29 are withdrawn from further consideration as discussed above, and claims 1-2, 4-7, and 11-12 are currently pending.

Information Disclosure Statement

6. The information disclosure statement (IDS) filed 09 January 2002 has been considered by the examiner.

Drawings

7. Applicants are advised that upon issuance of a patent, the complete text of the sequence listing submitted in compliance with 37 C.F.R.§§1.821-1.825 will be published as part of the patent. Therefore, it is unnecessarily redundant to repeat the sequence information in the form of Figures. Applicants should amend the specification to delete any Figures (e.g. Appendix 1-4, for example) which consist only of nucleic acid or protein sequences which have been submitted in their entirety in computer readable format (i.e. as SEQ ID NO:'s) and should further amend the specification accordingly to reflect the replacement of the Figure by the appropriate SEQ ID NO.

8. The drawings are objected to because Figure 1 is too dark for the Examiner to reasonably interpret. Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being

amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

9. The disclosure is objected to because of the following informalities: A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74 is required. See MPEP § 608.01(f). Appropriate correction is required.

Claim Objections

10. Claim 12 is objected to because of the following informalities: Claim 12 encompasses non-elected inventions, e.g., "a composition comprising an effective amount of a homer peptide interacting with the homer interaction motif located in the disease-associated target". Appropriate correction is required.

Claim Rejections - 35 USC § 112, 2nd paragraph

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-2 and 4-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. Claims 1 and 4 are indefinite because it is unclear what is meant by the terms "neuroleptic syndrome" and "neuroleptic induced disorders". The metes and bounds of these phrase are not defined in the Specification nor are limitations provided in the claim to clearly define said phrase, and it is unclear if "neuroleptic maligne syndrome" is intended or the claims encompass other, undefined disorders or syndromes associated with neuroleptics.

14. All remaining claims are rejected for depending from an indefinite claim.

Claim Rejections - 35 USC § 112

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claims 1-2, 4-7, and 11-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to a method for treatment of psychosis in a human comprising administering to said human haloperidol, does not reasonably

provide enablement for claims to a method for treatment of neuroleptic maligne syndrome or psychosis in a human comprising administering to said human any compound which modifies homer expression, nor for the treatment of an unspecified "disease" as recited in claim 12. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

17. The claims are drawn to a method for treatment of neuroleptic maligne disorder, psychosis, a CNS disorder, or "a disease" by administering a compound that modifies homer expression. The Specification teaches that administering haloperidol, a typical antipsychotic with a strong therapeutic effect on the treatment of psychosis (See 1, lines 21-24), to rats increases homer expression (See page 2, lines 36-38; Figures 2A-2C; page 6, lines 33-37). The Specification further teaches that homer protein is expressed in astrocytes. The Specification also teaches that homer interacts with the intracytoplasmic region of mGluR1a and mGluRr metabotropic glutamate receptors, and that administration of SIB-1893 and MPEP, selective mGluR5 antagonists, produces a dose-dependent antagonism of methamphetamine-induced hyperactivity (See page 10) and homer gene expression (See page 6, lines 37-39). The Specification asserts that compounds which induce homer protein expression are useful in treating a variety of diseases (See page 17, lines 25-28).

18. Enablement is not commensurate in scope with claims to a method of treatment using any compound that modifies homer expression. It is noted that the patentability of the claimed method rests on the particular compound that is being administered, not the mechanism of action of that compound. The specification as filed does not provide guidance or examples that would

enable a skilled artisan to use the disclosed methods for treatment of a disease comprising administering a compound that modifies homer expression other than haloperidol. The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to:

1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

19. The only evidence in the Specification is a teaching that administering haloperidol, a typical antipsychotic with a strong therapeutic effect on the treatment of psychosis (See 1, lines 21-24), to rats increases homer expression (See page 2, lines 36-38; Figures 2A-2C; page 6, lines 33-37). However, the person of ordinary skill in the art would not reasonably expect that any compound that has the singular effect of increasing homer expression would be useful for the treatment of any particular disease. The art teaches that haloperidol has side effects that include extrapyramidal symptoms, tardive dyskinesia, anticholinergic effects, and orthostatic hypotension (Vella-Brincat et al. (2204) Haloperidol in palliative care. Palliative Medicine. 18:195-201; Antipsychotic agents in Drug Facts and Comparisons., pages 971-977. 2002), and the specification as filed provides no nexus between homer expression and the pharmacological benefit of haloperidol.

20. Therefore, the person of ordinary skill in the art would not be able to use the method for treatment of neuroleptic maligne disorder, psychosis, a CNS disorder, or "a disease" by administering a compound that modifies homer expression because there is no reasonable

expectation that any compound that modifies homer expression would have the claimed property of treatment of neuroleptic maligne disorder, psychosis, a CNS disorder, or an unspecified "disease", which would include diseases having diverse etiologies and different windows of opportunity for treatment. In order to practice the invention using the specification and the state of the prior art as outlined above, the quantity of experimentation required to practice the invention as claimed would be undue.

Claim Rejections - 35 USC § 102

21. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

22. Claims 1-2, 4-5, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Pratt et al. (Trifluperidol and haloperidol in the treatment of acute schizophrenia. American Journal of Psychiatry 121:592-594. 1964). Pratt et al. teach the treatment of schizophrenia in humans comprising the administration of haloperidol. While Pratt et al. are silent with regards to modifying homer expression, it is noted that the mechanism of action of the compound as recited in the claims has not been given patentable weight.

23. Therefore, Pratt et al. teach all the limitations of claims 1-2, 4-5, and 12.

Summary

24. No claim is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback, Ph.D.** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

JML
January 21, 2005

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER